REMARKS

Reconsideration of the present Application in view of the Amendments submitted herewith and the following remarks is respectfully requested.

Claims 58-71 are presently pending. By entry of this amendment claims 58, 69 and 71-74 are pending. Claims 58, 69, and 70 have been amended and new claims 72-74 have been added to define more clearly certain embodiments of the invention. Claims 59-68 and 70 are hereby cancelled without acquiescence to any rejection and without prejudice to further prosecution of the subject matter in a related divisional, continuation, or continuation-in-part application. Support for these amendments is provided throughout the specification and, therefore, does not constitute new matter. Support for the amended claims may be found throughout the specification, for example, at page 17, lines 12-14; page 34, line 30 through page 35, line 7; page 35, lines 9-18; page 42, lines 14-22; page 45, lines 1-19; Tables 1, 2, and 4; and Figure 2.

Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 58-71 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Action asserts that the new claims contain new subject matter that was not described in the specification. Specifically, the Action asserts that the feature "on the same cell" recited in claims 58, 59, 62, 63, and 65 is not disclosed in the specification and is new matter.

Applicants respectfully traverse this basis of rejection and submit that the present claims as amended herein are described in the instant specification in sufficient detail such that a skilled artisan would appreciate that Applicants had possession of the invention as claimed and that no new matter has been introduced into the application. It is respectfully submitted that one of ordinary skill in the art would clearly appreciate that Applicants describe the use on the same cell. To this end, Applicants note that that technology can be applied to identifying a cell type (see page 6, line 3). Certainly, if each immunoglobulin were always binding to different and distinct cells, this wouldn't be useful in the least. Quite the contrary is true, it is examining the

differential pattern of recognition on each cell, which is one of the advantages of the present invention.

With respect to the specifically objected to language of "on the same cell" Applicants submit the specification is not required to describe each of the claim limitations exactly, "but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that applicants invented [the subject matter], including those limitations." *In re Wertheim*, 541 F.2d 257, 262; 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976). Furthermore, the claims "need not be described in *haec verba* to satisfy the description requirement." *In re Smith*, 458 F.2d 1389, 59 C.C.P.A. 1025, 173 U.S.P.Q. 679 (1972). It is clear that Applicants envisioned use of multiple binding agents on the same cell from at least pages 6, lines 3-5, page 11, lines 25-27, and page 13, lines 10-15 (noting another aspect of the invention is directed to a method for determining the presence of a disease condition or disorder or a propensity to develop a disease condition or disorder such as but not limited to cancer in an animal, avian species or plant, said method comprising obtaining a biological sample from said animal, avian species or plant comprising free binding partners or binding partners bound to ***a cell surface***, said binding partners associated directly or indirectly with said disease condition or disorder and contacting said biological sample with a solid support comprising an array of molecules capable of binding to said binding partners wherein the molecules are in an arrangement in said array such that upon interaction with the binding partners a differential pattern of density provides an identifiable signal which is indicative of the disease condition or disorder or a propensity to develop said disease condition or disorder). The ability to identify cell types, diagnose cancers, and diagnose conditions or disorders by examining "a cell surface" clearly includes the use of "the same cell". Nevertheless, while not acquiescing to this ground of rejection, Applicants have amended the claims to remove "the same cell" limitation, but reserve the right to re-introduce this amendment at a later time or in a subsequent continuation, divisional, or continuation-in-part application.

Applicants' presently claimed embodiment of the invention is related to an assay device for identifying a leukemia of T-cell, B-cell, or myeloid lineage in a subject. The device comprises (a) a solid support; and (b) an array of immunoglobulin molecules, or derivatives thereof, immobilized to discrete regions on the solid support (*see, e.g.,* specification, page 34,

line 30 through page 35, line 7). Each discrete region comprises an immunoglobulin, or derivative thereof, specific for a different cell surface antigen, wherein the array comprises immunoglobulin molecules, or derivatives thereof, specific for at least seven cell surface marker antigens, wherein the at least seven cell surface marker antigens are selected from the list in Table 4, and wherein the pattern of expression of the at least seven cell surface marker antigens on a leukocyte distinguishes leukemias of T-cell, B-cell, or myeloid lineage (*see, e.g.,* specification, page 45, lines 1-19; Tables 1, 2, and 4; and Figure 2).

Accordingly, Applicants submit that the present claims are fully supported by the instant specification and do not constitute new matter, thus meeting the written description requirements under 35 U.S.C. § 112, first paragraph. Applicants therefore respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 58-71 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Action concedes that the specification enables a device for determining the presence of cancer or a propensity to develop cancer in an animal comprising an array of immunoglobulin molecules that are specific for cell surface antigens from a population of CCRF-CEM T cell leukemia cells and Raji B cell lymphoma cells. The Action, however, alleges that scope of the claims is not commensurate with the disclosure in the specification and that undue experimentation would be required by a person skilled in the art to determine the specific combination of cell surface antigens to use for detection of diseases other than CCRF-CEM T cell leukemia and Raji B cell lymphoma.

Applicants respectfully traverse this rejection and submit that as disclosed in the specification and recited in the instant claims, Applicants fully enabled the presently claimed subject matter at the time the application was filed. Applicants' presently claimed invention is directed, in pertinent part, to an assay device for identifying a leukemia of T-cell, B-cell, or myeloid lineage in a subject. As discussed above, the device comprises (a) a solid support; and (b) an array of immunoglobulin molecules, or derivatives thereof, immobilized to discrete regions on the solid support. Each discrete region comprises an immunoglobulin, or derivative

thereof, specific for a different cell surface antigen, wherein the array comprises immunoglobulin molecules, or derivatives thereof, specific for at least seven cell surface marker antigens, wherein the at least seven cell surface marker antigens are selected from the list in Table 4, and wherein the pattern of expression of the at least seven cell surface marker antigens on a leukocyte distinguishes leukemias of T-cell, B-cell, or myeloid lineage.

As provided in the teachings of the application, the specification teaches a person skilled in the art how to make and use, without undue experimentation, a device for identifying and distinguishing different types of leukemias that are of T cell, B cell, or myeloid lineage (*see, e.g.,* specification, at page 42, lines 14-22; page 45, lines 1-18; page 61, lines 5-19; Table 4; Figures 5 and 7). The device comprises a solid support and an array of immunoglobulin molecules (or derivatives thereof) that are immobilized to the support by using methods described in the specification and practiced in the art (*see, e.g.,* page 34, line 30 through page 35, line 18; page 50, line 4 through page 51, line 13). The array comprises immunoglobulin molecules that are specific for at least seven different cell surface marker antigens, which may be selected from Table 4 (*see also, e.g.,* specification, page 45, lines 3-18; page 17, lines 12-14, and Figure 2). The specification teaches a person skilled in the art that the pattern of expression of these at least seven cell surface marker antigens on a leukocyte distinguishes leukemias that are of T cell, B cell, or myeloid lineage (*see, e.g.,* page 45, lines 3-18; page 61, lines 5-19; page 63, lines 21-24; Table 4; page 17, lines 12-14 and Figure 2; Figure 5; and Figure 7; *see also, e.g.,* page 26, lines 11-20; page 27, lines 4-18 and page 34, lies 12-16). Thus, the specification teaches a skilled artisan how to make and use the claimed device to distinguish a leukemia of T cell lineage (as represented, for example, by CCRF-CEM T cell leukemia (*see, e.g.,* page 61, lines 1-19; Table 4; Figure 7b)); a leukemia of B cell lineage (as represented, for example, by Raji B cell lymphoma (*see, e.g.,* page 61, lines 1-19; Table 4; Figure 7c)); and a leukemia of myeloid lineage (*see, e.g.,* page 61, lines 1-19; Table 4; Figure 7d)).

The Action asserts that the lack of disclosure directed to the expression of specific CD markers beyond the disclosed CDs for CCRF-CEM T cell leukemia and Raji B cell lymphoma, and the lack of requirement of criteria beyond CDs expression support that undue experimentation would be required to perform the invention. Without acquiescing to the asserted

grounds for rejection, Applicants have amended the claims to require at least seven surface marker specific immunoglobulins selected from the list in Table 4. One of skill in the art would readily recognize that given the limited number of markers listed in Table 4, that such a selection criteria clearly enables the claim and does not require the listing of any specific set of immunoglobulins. It is well-established precedent that the enablement requirement is met even if a considerable amount of experimentation is necessary, as long as such experimentation is not undue. In the present case, very little experimentation would be necessary to create usable combinations. In fact all that would be required would be the immunoglobulins and a solid support, as well as a means of laying down the immunoglobulins thereon (such as by a robotic micropipettor). Further one of skill in the art could readily conclude from the data contained in the instant case that any one of these combinations will likely result in a pattern that, while not always most optimal, will nevertheless yield valuable information regarding the type of leukemia present.

Accordingly, Applicants submit that given the disclosure of the present application, the specification enables a skilled artisan to make and use the claim device, readily and without undue experimentation. Applicants therefore respectfully submit that the application satisfies all requirements under 35 U.S.C. § 112, first paragraph, and request that the rejection of the claims be withdrawn.

Rejection Under 35 U.S.C. § 102(b)

Claims 58-62, 65, 66, and 68-70 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Yoshinari et al. (*Br. J. Cancer* 74:359-67 (1996)). The Action asserts that Yoshinari et al. describe an ELISA device comprising an array of four monoclonal antibodies that bind to different surface antigens present on A549 lung carcinoma cells. The Action further asserts that the feature of an "array" has not been specifically defined in the specification and that the description of the assay device in Yoshinari et al. anticipates the claimed device. The Action also alleges that the features after the term "when" are directed to a condition that does not structurally limit the claimed device and that the prior art device

inherently possesses these features. The Action further asserts that the features recited after the term "when" are inherent to the assay device described in Yoshinari et al.

Applicants respectfully traverse this rejection and submit that Yoshinari et al. fail to anticipate the presently claimed embodiment of the invention. Applicants' invention is directed in pertinent part to an assay device for identifying a leukemia of T-cell, B-cell, or myeloid lineage in a subject. The device comprises (a) a solid support; and (b) an array of immunoglobulin molecules, or derivatives thereof, immobilized to discrete regions on the solid support. Each discrete region comprises an immunoglobulin, or derivative thereof, specific for a different cell surface antigen, wherein the array comprises immunoglobulin molecules, or derivatives thereof, specific for at least seven cell surface marker antigens, wherein the at least seven cell surface marker antigens are selected from the list in Table 4, and wherein the pattern of expression of the at least seven cell surface marker antigens on a leukocyte distinguishes leukemias of T-cell, B-cell, or myeloid lineage.

Yoshinari et al. fail to teach each and every feature of the claimed assay device. The document fails to teach or suggest an assay device that comprises a solid support and an array of immunoglobulin molecules (or derivatives thereof), wherein each immunoglobulin molecule, or derivative thereof is immobilized to a discrete region on the solid support. Yoshinari et al. also fail to teach or suggest that the array comprises immobilized immunoglobulin molecules that specifically bind to at least seven different cell surface marker antigens, wherein the cell surface marker antigens are selected from Table 4 and wherein the pattern of expression of the at least seven cell surface marker antigens on a leukocyte distinguishes leukemias of T-cell, B-cell, and myeloid lineage.

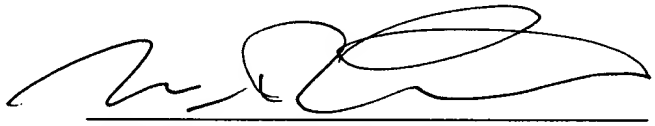
By contrast, Yoshinari et al. describe plating, culturing, and fixing cells from different carcinoma cell lines in microtiter plates; therefore, cells--not immunoglobulins as recited in the instant claims--are immobilized to a solid surface. Yoshinari et al. simply do not teach or suggest a device comprising a solid support to which an array of different immunoglobulins are immobilized that bind to at least seven different cell surface marker antigens.

Accordingly, Applicants respectfully submit that the claimed assay device meets the requirements for novelty under 35 U.S.C. § 102 and request that this rejection be withdrawn.

Applicants respectfully submit that all claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this case, the Examiner is invited to telephone the undersigned at 206-622-4900.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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